

C3 17. (once amended) The delivery system of claim 1, wherein said genetic material [is]encodes a protein.

C4 61. (new) The delivery system of claim 4, wherein said reservoir means further comprises a supply of conduction protein genetic material therein.

II. REMARKS TO THE AMENDMENTS

Support for the various amendments made to the claims herein may be found throughout the application as filed.

Claim 5 originally claimed two elements which were supported by the application. The original two elements are now found separately in Claim 5 and new Claim 61. Claim 5 is now solely directed to a distal end portion of the catheter comprising a hollow helical element. New claim 61 is directed to a reservoir containing a supply of the conduction protein genetic material. The reservoir containing a supply of the conduction protein genetic material was originally found part of claim 5.

Claim 10 has been amended to a "means for delivering a therapeutically effective amount" of the conduction protein from the reservoir. Support for d"elivering a therapeutic" effective amount is found on page 6, lines 21-24 and 24-25; page 7, 1st full paragraph, lines 1-4; page 10, lines 1-3 and lines 4-5; page 10, 1st full paragraph, lines 1-3; page 3 11, lines 18-19, lines 20-23 and 23 and 24; and page 25, 2nd full paragraph, lines 7-8, 13, and 16-17; and as generally taught throughout the specification.

Claim 17 has been amended to indicate that the genetic material encodes a protein. This is known by one skilled in art and as taught by the specification at page 23, line 27 and as generally taught throughout the specification.

III. REJECTIONS OF CLAIMS MADE IN THE FIRST OFFICE ACTION

In the communication from the Examiner mailed May 12, 2000, the Examiner rejected claims on the following bases:

- (1) Claims 56-60 were rejected under 35 U.S.C. Section 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention;
- (2) Claims 5, 10, 17-19, and 25 were rejected under 35 U.S.C. Section 112, second paragraph, as being indefinite to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
- (3) Claims 1-55 were rejected under 35 U.S.C. Section 103(a) as being unpatentable over Mulier et al (WO 95/05781) in view of Leiden et al (WO 94/11506) and Kanter et al (1994);

Response to each of the foregoing rejections are provided below, where each response references the number corresponding to each rejection set forth above.

IV. Responses to Rejections Made in the First Office Action

(1) Cancellation of Claims 56-60 render moot the rejections made under Section 112, first paragraph.

Applicants have cancelled, without prejudice, claims 56-60, thereby rendering the moot the rejection under section 112, first paragraph.

(2) Amendments to Claims 5, 10, 17-19, and 25 overcome the rejections made under 35 U.S.C. Section 112, second paragraph.

Claim 5 was found to be unclear as to the meaning of “reservoir means comprises said interior with said supply of conduction protein genetic material therein.” By use of the term comprising it was found to be unclear whether the reservoir is in the interior of the helical element, or that it can supply genetic material to the interior. Applicants claim 5 has been reformed into two claims. Claim 5 has been amended so as to be directed only to the aspect that the distal end portion comprises a hollow helical element. Claim 61 has been added to specifically include the aspect that the reservoir can be contained within the interior of the catheter.

Claim 10 was found to be unclear as to the metes and bounds of “means of forcing” genetic material from the reservoir. Claim 10 has been amended to a “means for delivering a therapeutically effective amount of said conduction protein genetic material from said reservoir means and out of said distal tip.” The replaced language makes clear that a therapeutically effective amount of the conduction protein genetic material is delivered by any suitable means.

Claim 17-19 were found unclear as to use of the term “genetic material is protein.” “Genetic” was pointed out to be an accepted term of art referring to genes and that which comprises either DNA or RNA and that “proteins” are material produced via transcription and translation. Claim 19 was amended to read so that the delivery system provides genetic material encoding a protein. Further, incorporation of the amended language makes clear in claims 18 and 19 that the encoded protein can be a cardiac gap junction protein or can be selected from the group consisting of Cx40, Cx43, and Cx45, respectively.

Claim 25 was found to be unclear as to the metes and bounds of “a peelable introducer sheath.” The application indicates at page 16, line 8, that the peelable introducer sheath is part of the catheter. One skilled in the art of catheter technology would understand that an “introducer sheath” helps introduce the catheter into a cavity (attorney search found the term introducer sheath in over 600 US patents posted by the USPTO at its web site). The term peelable is given its natural and understood adjectival meaning from the word peel as “to strip

off an outer layer or to remove by stripping.”¹ Thereby, a “peelable introducer sheath” would be understood to be a removable or strippable introducer sheath.

(3) Claims 1-25 and 39-55 are not obvious over Mulier et al (WO 95/05781) in view of Leiden et al (WO 94/11506) and Kanter et al (1994) because Mulier teaches away from the intended function of delivering genetic material to cardiac tissue and thereby is not a properly combinable reference.

Mulier describes an ablation catheter and method of performing cardiac ablation. Although the catheter described contains a hollow, helical electrode that is capable of being screwed in to cardiac tissue the device functions to destroy the surrounding tissue. The Mulier reference does not teach or suggest the use of the device for delivery of genetic material in place of the Ringer’s solution. Obviousness can not be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching, suggestion or incentive supporting the combination. *ACS Hospital Systems, Inc. v. Montefiore Hospital*, 732 F.2d 1572, 1577, 221 USPQ 929, 933 (Fed. Cir. 1984).

The present invention is directed to restoring or correcting conduction disturbances in cardiac tissues. One skilled in the art reading Mulier would not use the Mulier device for introducing genetic material for restoring cellular tissue. The Mulier device is described as an ablation catheter, wherein the essential goal is to destroy cardiac tissues, *i.e.*, to produce lesions. One would not use such a device to restore cardiac tissue and thereby one would not combine this device with the teaching of Leiden or Kanter to restore conductive cell function. Further, this is supported by the described function of the Mulier reservoir. Mulier uses the reservoir to deliver Ringer’s solution to improve conductivity to the area to be destroyed. Nowhere does Mulier suggest the reservoir as part of the delivery of genetic materials for the purpose of providing new conductive proteins to establish new cellular tissue. In fact, Mulier in essence teaches a device for destroying cellular conductivity and thereby teaches away from a device used to promote conductivity by providing new cellular tissue. As such, Mulier is not a properly combinable reference because the intended function of the Mulier device is to destroy tissue, and thereby there would be no technological motivation for combining Mulier with the other cited references. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984).

¹ Webster’s Seventh New Collegiate Dictionary.

V. CONCLUSION

Applicants respectively request allowance of claims 1-25 and 39-55, and 61. Applicants submit that all standing rejections under 112, first and second paragraph, have been addressed. Applicants submit that the claimed invention is non-obvious under 103(a) in view of their submitted arguments. Examination of the application in view of the submitted amendments and arguments is requested. The Examiner is respectfully requested to contact the undersigned by telephone at (763) 514-3279 with any questions or comments he may have.

Respectfully submitted,

Kenneth Stokes et al.

By their attorney

A handwritten signature in cursive script, appearing to read "Kenneth J. Collier", is written over a horizontal line.

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